GP 1643

Dkt. 50130-E/JPW/JSG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Daniel J. Capon, Jeannette M. Whitcomb and Neil T. Parkin

Serial No.: 09/126,559 Examiner: B. Brumback

Filed : July 30, 1998 Art Unit: 1643

For : COMPOSITIONS AND METHODS FOR DETERMINING ANTI-VIRAL DRUG SUSCEPTIBILITY AND RESISTANCE AND ANTI-VIRAL DRUG SCREENING

1185 Avenue of the Americas
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November 29, 1999

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12-8-99

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

COMMUNICATION IN REPLY TO SEPTEMBER 2, 1999 OFFICE ACTION AND PETITION FOR A TWO-MONTH EXTENSION OF TIME

This Communication is submitted in reply to the September 2, 1999 Office Action issued by the U.S. Patent and Trademark Office in connection with the above-identified application. A reply to the September 2, 1999 Office Action was originally due October 2, 1999. Applicants hereby requests a two-month extension of time for replying to the September 2, 1999 Office Action. The fee under 37 C.F.R. §1.17(a)(3) for a two-month extension of time is ONE HUNDRED AND NINTY DOLLARS ($190.00) for a small entity, and a check in this amount is enclosed. Applicants have previously established small entity status. A reply to the September 2, 1999 Office Action is now due December 2, 1999. Accordingly, this Communication is being timely filed.

In the September 2, 1999 Office Action, the Examiner to whom the subject application is assigned required restriction under 35 U.S.C. § 121 to one of the following allegedly independent and distinct inventions:

I. Claims 1, 4, 8, 37, 40, and 55-58 drawn to a methods for determining susceptibility for an HCV anti-viral drug;

II. Claims 20 and 25 drawn to Flaviviridae test vectors;

III. Claims 59, 62, 91, 92, 94, and 108-111 drawn to methods for determining susceptibility for an HCMV anti-viral drug; and

IV. Claim 77 drawn to a Herpesviridae test vector.

The Examiner stated that the inventions are distinct, each from the other because of the following reasons:

The Examiner stated that inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. §806.05(h)). The Examiner stated that in the instant case, the test vector of Group II can be used for determining susceptibility to antiviral drugs used for Flaviviridae other than HCV or could be used as an immunogen to raise antibodies against some component of the vector.

The Examiner stated that inventions III and IV are related as product and process of use. The Examiner stated that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. §806.05(h)). The Examiner stated that in the instant case the Herpesviridae test vector may be used for determining susceptibility to antiviral drugs for Herpesviridae other than HCMV.

The Examiner stated that the methods of groups I and III are patentably distinct processes having different goals.

The Examiner stated that the products of Groups II and IV have different structures and are used for different purposes.

The Examiner stated that because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. The Examiner stated that additionally, the search required for Group III is not required for Group I and the search for Group IV is not required for Group II.

In reply, applicants hereby elect Group I, claims 1, 4, 8, 37, 40, and 55-58 with traverse.

Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Contrary to the requirement of 35 U.S.C. §121, the Examiner has found that the inventions are distinct without also finding them to be independent inventions.

Under M.P.E.P. §802.01, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation and effect." The claims of Examiner's Group I drawn to methods for determining susceptibility for an HCV anti-viral drug are related to the claims of Examiner's Groups II, III and IV in that claims in all of the groups are related to a resistance test vector comprising a patient-derived segment which comprises a gene and an indicator gene. The claims of Examiner's Group I are drawn to a method for determining susceptibility for an HCV anti-viral drug and are related to the claims in Examiner's Group II, which are drawn to Flaviviridae test vectors and the claims in Examiner's Group IV, which are drawn to a Herpesviridae test vector since they all

relate to a resistance test vector comprising a patient-derived segment comprising a gene and an indicator gene. The hepatitis C virus gene of Group I claims, the Flavivirus gene of Group II claims and the Herpesviridae gene of group IV can be used equally in this invention as part of the resistance test vector. The resistance test vector means one or more vectors which taken together contain DNA or RNA comprising a patient-derived segment and an indicator gene. Thus, the claims of Groups I, II and IV are related.

The claims of Examiner's Group III, drawn to methods for determining susceptibility for an HCMV anti-viral drug are related to the claims of Examiner's Group I because the resistance test vector comprising a patient-derived segment is the same in both Groups I and III. Therefore, the claims of Examiner's Groups II and IV are related through their respective relation to the claims of Group I. The claims of Examiner's Group III, drawn to methods for determining susceptibility for an HCMV anti-viral drug are related to the claims of Examiner's Group I, drawn to methods for determining susceptibility for an HCV anti-viral drug since the method of determining susceptibility for an anti-viral drug is the same for both HCMV and HCV virus. Therefore, the claims of Examiner's Groups I and III are related. Accordingly, Examiner's Groups II and IV are thus related to Examiner's Group III through their relation to the claims of Examiner's Group I.

Applicants therefore respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicants point out that M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

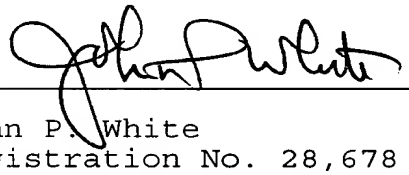
Applicants maintain that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Group I (methods for determining susceptibility for an HCV anti-viral drug) will reveal whether any prior art exists as to the Flaviviridae test vector (Group II); methods for determining susceptibility for an HCMV anti-viral drug (Group III); and a Herpesviridaev(Group IV). Since there is no burden on the Examiner to examine Groups I-IV in the subject application, the Examiner must examine the entire application on the merits.

Applicants maintain that claims 1, 4, 8, 20, 25, 37, 40, 55-59 and 77 define a single inventive concept. Accordingly, applicants respectfully request that the Examiner join Groups I-IV and examine claims 1, 4, 8, 20, 25, 37, 40, 55-59, 62, 77, 91, 94, and 108-111.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone at the number provided below.

No fee other than the $190.00 fee for a two-month extension of time is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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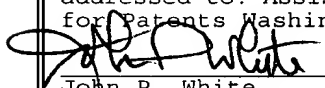
I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents Washington, D.C. 20231.



11/29/99

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